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IMPLEMENTATION OF INTERNATIONAL DRUG CONTROL TREATIES

Report of the Secretary-General

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*E/CN.7/1991/1/Rev.1.

I. CONSIDERATION OF NOTIFICATIONS RECOMMENDING RESCHEDULING OR DESCHEDULING UNDER ARTICLE 2 OF THE CONVENTION ON PSYCHOTROPIC SUBSTANCES, 1971

A. Notification recommending rescheduling

1. Pursuant to article 2, paragraphs 1 and 6, of the Convention on Psychotropic Substances, 1971, 1/ the Director-General of the World Health Organization (WHO) notified the Secretary-General on 22 October 1990 that WHO was of the opinion that delta-9-tetrahydrocannabinol (delta-9-THC) and its stereochemical variants should be rescheduled from Schedule I to Schedule II of the Convention. For the text of the WHO notification, and relevant information in support of its recommendation, as contained in the report of the WHO 27th Expert Committee on Drug Dependence, see annex I.

2. In accordance with article 2, paragraph 2, of the Convention on Psychotropic Substances, 1971, 1/ the Secretary-General transmitted to all Governments by a note (NAR/CL.21/1990) dated 8 November 1990 the text of that notification, as well as advance excerpts from the report of the 27th Expert Committee. Governments were asked to indicate any economic, social, legal, administrative or other factors they considered relevant to the possible rescheduling of this substance.

3. The Secretary-General also drew the attention of Governments to the fact that a recommendation to transfer delta-9-THC from Schedule I to Schedule II of that Convention had already been examined by the 26th Expert Committee in 1989, which recommended to the Director-General of WHO that only dronabinol, one of the stereochemical variants of delta-9-THC, should be so transferred. Governments were also informed that the Commission on Narcotic Drugs, at its eleventh special session in 1990, had considered the proposal and had decided not to transfer dronabinol from Schedule I to Schedule II. 2/

4. By 10 December 1990, replies to the Secretary-General's note had been received from four countries. 3/ Two of the countries 4/ did not have any comments; one 5/ was in favour of the WHO recommendation, while in the reply from the fourth country 6/ stated that, should the Commission decide to reschedule delta-9-THC and its stereochemical variants, at the national level that country would consider dronabinol only as a Schedule II substance.

5. The notification by the Director-General of WHO is now before the Commission in accordance with article 2, paragraphs 5 and 6, of the Convention on Psychotropic Substances, 1971. 1/ Those paragraphs read:

> "5. The Commission, taking into account the communication from the World Health Organization, whose assessments shall be determinative as to medical and scientific matters, and bearing in mind the economic, social, legal, administrative and other factors it may consider relevant, may add the substance to Schedule I, II, III or IV. The Commission may seek further information from the World Health Organization or from other appropriate sources.
>
> "6. If a notification under paragraph 1 relates to a substance already listed in one of the Schedules, the World Health Organization shall communicate to the Commission its new findings, any new assessment of the substance it may make in accordance with paragraph 4 and

any new recommendations on control measures it may find appropriate in the light of that assessment. The Commission, taking into account the communication from the World Health Organization as under paragraph 5 and bearing in mind the factors referred to in that paragraph, may decide to transfer the substance from one Schedule to another or to delete it from the Schedules."

6. The Commission should therefore decide whether to transfer delta-9-THC and its stereochemical variants from Schedule I to Schedule II of the Convention as recommended by WHO, and if not, what other action, if any, is required.

B. Notification recommending descheduling

7. Pursuant to article 2, paragraph 1, of the Convention on Psychotropic Substances, 1971, 1/ the United States of America conveyed to the Secretary-General, by a note dated 21 August 1986, its opinion that the substance propylhexedrine (N, [illegible]methylcyclohexaneethylamine) should be deleted from Schedule IV of the Convention and not be transferred to any other schedule of the Convention.

8. In accordance with article 2, paragraph 2, of the Convention, the Secretary-General transmitted the notification to all Governments by a note (NAR/CL.10/1986) dated 17 November 1986, as well as the supporting information submitted by the United States.

9. Pursuant to article 2, paragraph 2, of the Convention, the Secretary-General also transmitted the text of that notification to WHO for consideration by its 25th Expert Committee on Drug Dependence in April 1988.

10. The 25th Expert Committee, on the basis of the data available, recommended to the Director-General of WHO deferral of consideration and a further review in two years' time.

11. The 27th Expert Committee accordingly re-examined this question in September 1990 and, on the basis of new data, recommended to the Director-General of WHO that propylhexedrine be removed from international control under the Convention on Psychotropic Substances, 1971. 1/

12. In accordance with article 2, paragraphs 1 and 6, of that Convention, WHO conveyed to the Secretary-General on 22 October 1990 its opinion that propylhexedrine should be removed from international control under the Convention.

13. Pursuant to article 2, paragraph 2, of the Convention, the Secretary-General, in a note (NAR/CL.20/1990) dated 8 November 1990, transmitted its notification and all supporting information to all Governments. The Governments were asked to indicate any economic, social, legal, administrative or other factors they considered relevant to the possible descheduling of the substance. For the text of the WHO notification, as well as relevant supporting information contained in the report of the 27th Expert Committee, see annex II.

14. By 10 December 1990, replies to the Secretary-General's note had been received from three countries. 7/ One country 5/ had no objection to the proposal; another 8/ did not agree with the WHO recommendation, pointing out

READEX FICHE

that the deletion of the substance from the schedule would raise administrative problems in that country; in the third country, 6/ the substance was reported to be unavailable.

15. The WHO notification referred to in paragraph 12 above is now before the Commission in accordance with article 2, paragraphs 5 and 6, of the Convention on Psychotropic Substances, 1971. 1/ (For the text of those paragraphs, see paragraph 5 above.)

16. The Commission should therefore decide whether to delete propylhexedrine from Schedule IV as recommended by WHO and, if not, what other action, if any, is required.

II. CONSIDERATION OF A NOTIFICATION PROPOSING THE TERMINATION OF EXEMPTIONS GRANTED UNDER THE PROVISIONS OF ARTICLE 3 OF THE CONVENTION ON PSYCHOTROPIC SUBSTANCES, 1971

Exemptions granted by the Government of the United States of America

17. Article 3 of the Convention on Psychotropic Substances, 1971 1/ provides that, if specific conditions are met, a party may decide to exempt preparations containing certain psychotropic substances from various control measures. In article 3, paragraph 2, of the Convention it is stipulated that:

> "2. If a preparation containing a psychotropic substance other than a substance in Schedule I is compounded in such a way that it presents no, or a negligible, risk of abuse and the substance cannot be recovered by readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health and social problem, the preparation may be exempted from certain of the measures of control provided in this Convention in accordance with paragraph 3."

A party which decides to exempt a preparation under article 3, paragraph 2, must notify the Secretary-General of that decision, of the name and composition of the exempted preparation, and of the control measures from which it is exempted. The Secretary-General transmits each such notification to the other Parties to the Convention, to WHO and to the International Narcotics Control Board. WHO examines the exemptions granted and, if it feels that an exemption is not justified, may recommend to the Commission that it terminate the exemption. Article 3, paragraph 4, stipulates in part that:

> "4. If a Party or the World Health Organization has information regarding a preparation exempted pursuant to paragraph 3 which in its opinion may require the termination, in whole or in part, of the exemption, it shall notify the Secretary-General and furnish him with the information in support of the notification. The Secretary-General shall transmit such notification, and any information which he considers relevant, to the Parties, to the Commission and, when the notification is made by a Party, to the World Health Organization. The World Health Organization shall communicate to the Commission an assessment of the preparation in relation to the matters specified in paragraph 2, together with a recommendation of the control measures, if any, from which the preparation should cease to be

exempted. The Commission, taking into account the communication from the World Health Organization, whose assessment shall be determinative as to medical and scientific matters, and bearing in mind the economic, social, legal, administrative and other factors it may consider relevant, may decide to terminate the exemption of the preparation from any or all control measures ..."

18. On 12 June 1989, the United States notified the Secretary-General that the Government, pursuant to article 3, paragraph 3, of the Convention on Psychotropic Substances, had decided to exempt 111 preparations containing psychotropic substances (butalbital, chlordiazepoxide, phenobarbital and secbutabarbital)* from various control measures set forth in that Convention, except for the mandatory measures required by article 3, paragraph 3(a)-(f), and for the requirements of article 9. Preparations containing substances in Schedule III had also been exempted from the requirements of article 12, paragraph 2.

*Note: The following list comprises all the 111 preparations proposed for exemption by the United States. Omission of the composition of the preparations accounts for the apparent repetitions. The 55 preparations before the Commission for its consideration, containing butalbital, are listed with their composition in annex IV.

Acetaminophen 325 mg, butalbital 50 mg; acetaminophen 500 mg, butalbital 50 mg; amaphen, reformulated; anolor 300; anoquan, modified formula; axotal; B-A-C; bancap; Blue Cross butalbital, APAP and caffeine; bucet; bucet; butace; butacet; butalbital and acetaminophen; butalbital and acetaminophen tablets 50/325; butalbital and acetaminophen tablets 50/650; butalbital with acetaminophen, caffeine; butalbital, acetaminophen or caffeine; butalbital, APAP and caffeine; butalbital, acetaminophen, caffeine; butalbital, acetaminophen and caffeine; butalbital, acetaminophen and caffeine II; butalbital compound; con-ten; dolmar; endolar; esgic; esgic; esgic forte; ezol; fabophen; febridyne plain; femcet; fioricet; G-1 capsules; IDE-cet; isocet; isopap; margesic; medigesic; pacaps; pacaps, modified formula; phrenilin; phrenilin forte; repan; repan; rogesic; sangesic; sedapap-10; tencet; tencet; triad; triad; triaprin; two-dyne revised; chlordiazepoxide HCl and clidinium bromide; chlordiazepoxide with clidinium bromide; chlordiazepoxide HCl 5 mg clinidium bromide 2.5 mg; chlordinium; chlordinium sealets; C.D.P. plus; clindex; clinibrax; clinoxide; librax; menrium 5-2; menrium 5-4; menrium 10-4; antispas; anti-spas elixir; anti-spas tablets; antispasmodic elixir; antispasmodic tablets; antispasmodic tablets; antracol; antrocol; antrocol; arco-lase plus; atropine sulfate with phenobarbital; barbeloid yellow; belladenal; belladenal-S; belladonna alkaloids with phenobarbital; belladonna alkaloids with phenobarbital; belladonna alkaloids with phenobarbital; bel-phen-ergots; bladder mixture plus phenobarbital; charspast; donna-sed; espasmotex; G.B.S.; hyosital white; hypnaldyne; isolate compound elixir; isophed; panzyme; phedral C.T.; private formula No. 3095; pulsaphen; spastolate; spastrin; theophenyllin; truxaphen; wescophen S-II; wesmatic forte; broncomar; butibel; butibel; digestokraft; quibron plus; quibron plus.

19. In accordance with article 3, paragraph 4, of the Convention, the Secretary-General transmitted that notification to all Governments by a note (NAR/CL.19/1989) dated 30 November 1989, inviting comments. WHO was informed thereof by a note from the Division of Narcotic Drugs dated 18 December 1989.

20. By 17 September 1990, replies had been received from 17 countries. 9/ In one country 10/ those preparations were reported to be neither imported, nor abused or seized. In two, 11/ only one of the 111 preparations listed containing chlordiazepoxide was available. In one of the two countries 12/ there was no objection to the exemptions and all preparations containing butalbital, chlordiazepoxide and phenobarbital were reported to be subject to national control measures. In two countries, 13/ it was reported that none of the substances contained in the exempted preparations, with the exception of chlordiazepoxide, which was available on prescription, were to be found and all preparations containing psychotropic substances were subject to national control measures. In one country, 14/ it was reported that preparations containing any of those four substances were available only on prescription. In five countries 15/ there was no objection to the exemptions, while two 16/ did not agree with them. Another country 6/ did not agree with the exemption of certain control measures for combinations of butalbital with acetaminophen and/or caffeine. One 5/ reported that the proposal to exempt the 111 preparations ran counter to the resolutions adopted by the Commission on Narcotic Drugs, and proposed that they should not be exempted from the provisions of paragraph 2, article 12, of that Convention. One 17/ expressed the view that all preparations containing analgesics and barbiturates should only be available on medical prescription and that those preparations should not be exempted from the provisions of article 10, paragraph 2.

21. In accordance with article 3, paragraph 4, of the Convention, the Director-General of WHO notified the Secretary-General on 22 October 1990 that WHO had recommended that the exemption of the 55 preparations containing butalbital be terminated, so that the requirements of article 12, paragraph 2, of the 1971 Convention should apply to those preparations. For the text of the WHO notification with supporting information, contained in the report of the 27th Expert Committee, see annex III. For the exact composition of the 55 preparations containing butalbital, as communicated by the United States of America in its notification of 12 June 1989, see annex IV.

22. The Secretary-General accordingly transmitted that notification to all Governments, together with supporting information, in a note (NAR/CL.19/1990) dated 8 November 1990, inviting them to indicate any economic, social, legal, administrative or other factors they considered relevant to the termination of the exemptions concerning the 55 preparations containing butalbital.

23. By 10 December 1990, replies had been received by the Division of Narcotic Drugs from five countries. 18/ Four 19/ were in agreement with the WHO recommendations. Of those four, one 5/ said that the preparations should not be exempted from the provisions of paragraph 2, article 12, of the Convention; another 6/ reported that combinations of butalbital with acetaminophen and/or caffeine should not be exempted from certain control measures of the Convention. One 8/ had no comments on this question.

24. In accordance with article 3, paragraph 4, of the Convention on Psychotropic Substances, set forth in paragraph 17 above, the Commission should therefore decide whether to terminate any or all the exemptions recommended by WHO, and, if not, what other action, if any, is required.

Notes

1/ United Nations, Treaty Series, vol. 1019, No. 14956.

2/ Official records of the Economic and Social Council, 1990, Supplement No. 4 (E/1990/24), chap. III, sect. A, paras. 51-54.

3/ Belgium, Japan, Norway and Switzerland.

4/ Japan and Norway.

5/ Belgium.

6/ Switzerland.

7/ Belgium, Japan and Switzerland.

8/ Japan.

9/ Belgium, Burkina Faso, Brunei Darussalam, Cameroon, Canada, Finland, Indonesia, Italy, Philippines, Portugal, Rwanda, Suriname, Sweden, Switzerland, Thailand, Togo and United Arab Emirates.

10/ Burkina Faso.

11/ Italy and Sweden.

12/ Italy.

13/ Philippines and Portugal.

14/ United Arab Emirates.

15/ Brunei Darussalam, Canada, Indonesia, Rwanda and Suriname.

16/ Cameroon and Thailand.

17/ Finland.

18/ Belgium, Cameroon, Japan, Switzerland and Turkey.

19/ Belgium, Cameroon, Switzerland and Turkey.

Annex I

NOTIFICATION FROM THE DIRECTOR-GENERAL OF THE WORLD HEALTH ORGANIZATION CONCERNING DELTA-9-TETRAHYDROCANNABINOL AND ITS STEREOCHEMICAL VARIANTS AND RELEVANT INFORMATION IN SUPPORT OF HIS RECOMMENDATION

Note addressed to the Secretary-General by the Director-General of the World Health Organization on 22 October 1990

The Director-General of the World Health Organization presents his compliments to the Secretary-General of the United Nations and has the honour to transmit, in accordance with Article 2, paragraphs 1 and 6, of the Convention on Psychotropic Substances, 1971, assessments and recommendations of the World Health Organization, as set forth in the annex hereto, concerning proposed international control in respect of delta-9-tetrahydrocannabinol and its stereochemical variants.

Summary of the recommendations arising out of the 27th Expert Committee on Drug Dependence

Delta-9-tetrahydrocannabinol and its stereochemical variants

1. Introduction

Dronabinol [INN, CAS 1972-08-3, for (-)-trans-delta-9-tetrahydrocannabinol], the active principle of cannabis, is included in Schedule I of the Convention on Psychotropic Substances, 1971. Dronabinol was reviewed by WHO in 1989 in response to a notification by the Government of the United States of America, requesting the transfer of all delta-9-tetrahydrocannabinols (delta-9-THC) from Schedule I to Schedule II of the Convention. Based on data available at that time, it was recommended that only dronabinol be rescheduled from Schedule I to Schedule II.

The United Nations Commission on Narcotic Drugs did not endorse this recommendation. Some delegations pointed out that the value of dronabinol in therapy did not seem to counterbalance its high potential for abuse, which would constitute a serious disadvantage if dronabinol would be moved to Schedule II. It was suggested, however, that WHO should continue collecting data on its therapeutic usefulness for another review.

WHO reviewed additional data compiled on therapeutic usefulness, and reconsidered its abuse potential and possible implications of rescheduling, bearing in mind the various concerns expressed by the Commission on Narcotic Drugs.

2. Assessment of therapeutic usefulness

Dronabinol is an effective antiemetic in the management of cancer chemotherapy-induced nausea and vomiting, with efficacy similar to that of oral phenothiazines. There is evidence that when used in combination with phenothiazines efficacy is enhanced and side-effects are reduced. There are limited data comparing dronabinol with the most effective antiemetic regimens used today to manage chemotherapy-induced nausea and vomiting. There are some data which indicate that dronabinol is less effective than intravenous metoclopramide when used in the treatment of nausea and vomiting caused by highly

emetogenic cancer chemotherapy drugs. There are no adequate comparative data on dexamethasone or $5HT_3$-receptor blockers. It should be noted, however that the 5-HT_3 blockers are not as yet generally available.

Dronabinol causes various adverse reactions due to its effects on the central nervous system. Although the frequent occurrence of these side-effects lessens its value as a therapeutic agent, dronabinol currently has a real but limited place in the management of chemotherapy-induced nausea and vomiting and may be useful in patients refractory to other antiemetics.

It is concluded that dronabinol has therapeutic usefulness definitely greater than that of the other substances in Schedule I, which have "very limited, if any" therapeutic usefulness, and comparable to a number of drugs in Schedule II.

However, the therapeutic usefulness of dronabinol, which is based on the balance between its therapeutic benefits and adverse consequences, may vary from country to country depending on a number of factors such as the prevalence of cancer and the extent of use of cancer chemotherapy as well as the supply of pharmaceutical products in general.

3. Assessment of abuse liability and public health and social consequences of abuse of dronabinol

The pharmacology of dronabinol is regarded to be identical to that of cannabis since the psychoactive pharmacological effects of cannabis are attributable to the effects of this substance. However, the likelihood of actual abuse and adverse public health and social consequences of dronabinol and/or synthetic THC is assessed to be substantially lower than that of cannabis, based on an examination of other determinants of the abuse liability which involve social factors such as popularity, availability, and price.

Reports on actual abuse of dronabinol and its public health and social consequences are nil. Introduction of pure delta-9-tetrahydrocannabinols into the illicit market place through illicit production is not economically viable either by synthesis or extraction from plant materials. As a matter of fact, no single case of clandestine manufacturing of dronabinol has been reported in the United States of America and only one minor report worldwide. Also, diversion of dronabinol preparations are extremely rare; only one case of diversion and some cases of theft have been reported in the United States of America since the drug was marketed in 1986.

Thus, it was concluded that the extent of the risk that might be caused by abuse of licit and illicit synthetic THC will not be especially serious particularly in the light of the massive volume and relatively low cost of cannabis in the illicit market place.

4. Assessment of the possibility of dronabinol's transfer to Schedule II leading to an increase in its abuse

Substances in Schedule II of the Convention on Psychotropic Substances, 1971 are subject to strict control measures similar to those applicable to narcotic drugs in Schedule I of the Single Convention on Narcotic Drugs, such as morphine. Although it is likely that the licit supply and use of dronabinol will increase, it is reasonable to predict that its abuse or diversion into

illicit traffic will remain insignificant based on the experience in the countries where it is already marketed. This may also be inferred from the absence of evidence of significant abuse of nabilone, a synthetic homologue of dronabinol with a similar pharmacological profile which is not controlled at the international level, in spite of its marketing in several countries since 1983.

With regard to the possibility of increasing the abuse of illicit dronabinol or clandestinely manufactured delta-9-THC, it is unlikely that the change in the scheduling status of dronabinol will favour the economic viability of its clandestine manufacturing in view of the massive availability of cannabis, a strong competitor of natural origin, at relatively low cost.

5. Assessment of the possibility of dronabinol's transfer to Schedule II leading to an increase in the abuse of cannabis

Since cannabis is controlled under the Single Convention on Narcotic Drugs, there will be no change in the control status of cannabis. Nevertheless, there might be a concern about the possibility that the official recognition of therapeutic usefulness of dronabinol might encourage the "medicinal" use of cannabis and thus its abuse. However, cannabis is already the most widely abused illicit drug in the world, with an annual seizure figure of 30,000 to 40,000 tons. It is unlikely that such recognition will make a significant difference to the current level of massive cannabis abuse.

6. Scope of recommendation

Although the data on the therapeutic usefulness and dependence liability relate only to one stereochemical variant of delta-9-tetrahydrocannabinol (dronabinol), it was noted that making a distinction between the one single isomer and the others contained in this group may create legal and forensic analytical problems in some countries. For this reason, it is recommended that delta-9-THC and its stereochemical variants be rescheduled together.

7. Recommendation

It is recommended that delta-9-tetrahydrocannabinol and its stereochemical variants be rescheduled from Schedule I to Schedule II of the Convention on Psychotropic Substances, 1971.

Annex II

NOTIFICATION FROM THE DIRECTOR-GENERAL OF THE WORLD HEALTH ORGANIZATION CONCERNING PROPYLHEXEDRINE AND RELEVANT INFORMATION IN SUPPORT OF HIS RECOMMENDATION

Note addressed to the Secretary-General by the Director-General of the World Health Organization on 22 October 1990

The Director-General of the World Health Organization presents his compliments to the Secretary-General of the United Nations and has the honour to transmit, in accordance with Article 2, paragraphs 1 and 6, of the Convention on Psychotropic Substances, 1971, assessments and recommendations of the World Health Organization, as set forth in the annex hereto, concerning proposed international control in respect of propylhexedrine.

Summary of the recommendations arising out of the 27th Expert Committee on Drug Dependence

Propylhexedrine

1. Substance identification

Propylhexedrine (INN, CAS 101-40-6) is chemically N, α-dimethylcyclohexaneethylamine. It has one chiral carbon atom in the molecule, so that two stereoisomeric forms and one racemate are possible.

2. Similarity to already known compounds and effects on the central nervous system

Animal pharmacological studies indicated that propylhexedrine has some stimulant actions, for example on locomotor activity and pressor effects, in common with amfetamine.

In humans, propylhexedrine produced pressor and stimulant effects similar to those of (+)-amfetamine but was significantly less potent. Administered by inhalation, propylhexedrine had local vasoconstrictor activity similar to that of ephedrine, but the duration of the activity was longer. Mucosal rebound congestion and chronic rhinitis may occur following excessive use of propylhexedrine in nasal inhalers. Amfetamine-like intoxication symptoms have been observed after oral or intravenous abuse.

3. Dependence potential

Studies in rats infused with propylhexedrine indicated that it acts as a typical stimulant of the central nervous system to which some tolerance develops. In drug-discrimination studies, propylhexedrine produced complete generalization to amfetamine in monkeys but only partial generalization in pigeons. It was self-administered by monkeys trained to self-administer cocaine, but at much lower response rates.

There have been no controlled laboratory studies of the dependence potential of propylhexedrine in human subjects.

4. Actual abuse and/or evidence for likelihood of abuse

Oral and intravenous abuse of propylhexedrine has been documented over a period of about 30 years, usually in the form of single case reports. Some of these reports mention severe adverse reactions after intravenous use, including myocardial infarction, "shock lung" syndrome and death. Since 1988 when WHO last reviewed propylhexedrine, more information has become available on the incidence of abuse. People who abuse a variety of drugs on a chronic basis do not find the subjective effects of propylhexedrine very appealing and rarely bother to use it despite its easy availability. The Drug Abuse Warning Network of the United States of America reported two emergency room and one medical examiner mentions for propylhexedrine from 1988 to 1989. Earlier data from the Drug Abuse Warning Network were also considered. This network has not detected a significant amount of propylhexedrine abuse over the past seven years. The threshold for inclusion in the list of "most frequently mentioned drugs" (which recently contained 256 drugs) is ten reported episodes of abuse in any one year. Propylhexedrine did not exceed this threshold in 1983, 1984, 1986, 1987, 1988 or 1989. Since 1982, there have been only 50 mentions of propylhexedrine abuse out of a total of a million reported episodes of drug abuse. These mentions were considered in relation to production within the USA and Canada of about 2,500,000 inhalers (approximately equivalent to 100 kg) annually, all of which were readily available on an over-the-counter basis. Since 1988, illicit traffic has been reported in only two countries. In the Federal Republic of Germany, only one prescription forgery was reported. In the USA, 4 cases involving propylhexedrine were reported. Three cases primarily involving seizures of small amounts (a total of 8.8 grams) of propylhexedrine from facilities described as "clandestine laboratories", and 2 nasal inhalers.

Based on these recent trends and the length of time that propylhexedrine has been available, it has been concluded that propylhexedrine is not likely to be abused so as to constitute significant public health and social problems. However, it is considered desirable not to make propylhexedrine available over-the-counter in forms other than an inhaler.

5. Therapeutic usefulness

Propylhexedrine is used in an inhalant form for nasal decongestion. An oral formulation of the hydrochloride has been used as an anorectic agent in the treatment of obesity. A number of alternative drugs are available for both these indications. The therapeutic usefulness of propylhexedrine is rated as little to moderate.

6. Recommendation

Based on new data documenting that the incidence of abuse and trafficking was still very low thus confirming the absence of any significant public health problems, it is recommended that propylhexedrine be removed from international control under the Convention on Psychotropic Substances, 1971.

Annex III

NOTIFICATION FROM THE DIRECTOR-GENERAL OF THE WORLD HEALTH ORGANIZATION CONCERNING EXEMPTIONS OF PREPARATIONS BY THE GOVERNMENT OF THE UNITED STATES OF AMERICA AND RELEVANT INFORMATION IN SUPPORT OF HIS RECOMMENDATION

Note addressed to the Secretary-General by the Director-General of the World Health Organization on 22 October 1990

The Director-General of the World Health Organization presents his compliments to the Secretary-General of the United Nations and, with reference to his note verbale (DND 421/12(2) USA) dated 18 December 1989, has the honour to transmit, in accordance with Article 3, paragraph 4 of the Convention on Psychotropic Substances, 1971, an assessment and recommendation of the World Health Organization, as set forth in the annex hereto, concerning the preparations exempted from certain control measures by the Government of the United States of America.

Summary of the recommendations arising out of the 27th Expert Committee on Drug Dependence

Exempted Preparations by the United States of America

1. Outline of exempted preparations

A total of 111 preparations, 55 containing butalbital and 56 containing either chlordiazepoxide, phenobarbital, secbutabarbital or their salts, have been exempted from various control measures by the Government of the United States of America. Butalbital is in Schedule III of the Convention on Psychotropic Substances, 1971, and the other cited substances are in Schedule IV of the same Convention. Those preparations containing barbiturates are compounded with such drugs as antipyretic analgesics, anticholinergics, ephedrine and xanthines in varying quantities. Those of chlordiazepoxide or its salt are compounded either with sodium estrone sulfate or clidinium bromide. The rationale applied by the exempting authorities of the United States of America is based on the concept of combining with the controlled substance an amount of counteractive drug sufficient to cause early subjective deterrent effects.

2. Assessment and Recommendation

There is some concern about the possibility that some of the 111 preparations, or some substances extracted from them, will be abused so as to constitute significant public health and social problems if exported to another country. Although they are reported to have caused no significant abuse problems in the exempting country, their possible exportation requires a more careful review in the future in order to determine whether termination of the exemption of some of these preparations will be needed.

It is also noted that the Guidelines for the Exemption of Preparations from Certain Control Measures under the Provisions of Article 3 of the 1971 Convention on Psychotropic Substances, adopted by the Commission on Narcotic Drugs in 1984, a/ state that there should be no exemption from the requirements of article 12, export declarations, and of article 10, paragraph 2, prohibition of advertisement to the general public (unless such

exemption would be in keeping with national statutatory requirements). In this regard, the exemption with respect to the 55 preparations containing butalbital from the requirement of article 12 is inconsistent with the 1984 Guidelines, although it would appear that the requirement of article 10, paragraph 2 is met anyway by the national requirements applicable to products sold only on prescription.

As a result of the above, it is recommended that the exemption of the 55 preparations containing butalbital from the requirement of article 12, paragraph 2, be terminated.

It would also be desirable if appropriate measures were taken by the Government of the United States of America to ensure that none of the 111 preparations would be exported without appropriate notice to the authorities of the importing country until such time that WHO can conduct a systematic review of the exemptions. This would be consonant with resolution 1987/30 "Improvement of the control of international trade in psychotropic substances listed in Schedules III and IV of the 1971 Convention", adopted by the Economic and Social Council of the United Nations in 1987.

Note

a/ Official Records of the Economic and Social Council, 1984, Supplement No. 3 (E/1984/13), chap. VIII, resolution 1 (S-VIII).

Annex IV

EXEMPTED PREPARATIONS CONTAINING BUTALBITAL TO BE CONSIDERED BY THE COMMISSION, WITH THEIR COMPOSITION

Name of exempted preparation Nom de la préparation exemptée Nombre del preparado exento	Composition of exempted preparation Composition de la préparation exemptée Composición del preparado	
Acetaminophen 325 mg, butalbital 50 mg	Acetaminophen Butalbital	325.0 mg 50.0 mg (per tablet)
Acetaminophen 500 mg, butalbital 50 mg	Acetaminophen Butalbital	500.0 mg 50.0 mg (per tablet)
Amaphen, reformulated	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Anolor 300	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Anoquan, modified formula	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Axotal	Acetaminophen Butalbital	650.0 mg 50.0 mg (per tablet)
B-A-C	Aspirin Butalbital Caffeine	650.0 mg 50.0 mg 40.0 mg (per tablet)
Bancap	Acetaminophen Butalbital	325.0 mg 50.0 mg (per capsule)
Blue Cross butalbital, APAP and caffeine	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per tablet)
Bucet	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per tablet)

continued

Name of exempted preparation Nom de la préparation exemptée Nombre del preparado exento	Composition of exempted preparation Composition de la préparation exemptée Composición del preparado	
Bucet	Acetaminophen Butalbital	650.0 mg 50.0 mg (per capsule)
Butace	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Butacet	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Butalbital and acetaminophen	Acetaminophen Butalbital	325.0 mg 50.0 mg (per tablet)
Butalbital and acetaminophen tablets 50/325	Acetaminophen Butalbital	325.0 mg 50.0 mg (per tablet)
Butalbital and acetaminophen tablets 50/650	Acetaminophen Butalbital	650.0 mg 50.0 mg (per tablet)
Butalbital with acetaminophen, caffeine	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per tablet)
Butalbital, acetaminophen or caffeine	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per tablet)
Butalbital, APAP and caffeine	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per tablet)
Butalbital, acetaminophen caffeine	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)

continued

Name of exempted preparation Nom de la préparation exemptée Nombre del preparado exento	Composition of exempted preparation Composition de la préparation exemptée Composición del preparado	
Butalbital, acetaminophen and caffeine	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per tablet)
Butalbital, acetaminophen and caffeine II	Acetaminophen Butalbital Caffeine	500.0 mg 50.0 mg 40.0 mg (per tablet)
Butalbital compound	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Con-ten	Acetaminophen Butalbital	650.0 mg 50.0 mg (per capsule)
Dolmar	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Endolar	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Esgic	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Esgic	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per tablet)
Esgic forte	Acetaminophen Butalbital Caffeine	500.0 mg 50.0 mg 40.0 mg (per tablet)
Ezol	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)

continued

Name of exempted preparation Nom de la préparation exemptée Nombre del preparado exento	Composition of exempted preparation Composition de la préparation exemptée Composición del preparado	
Fabophen	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per tablet)
Febridyne plain	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Femcet	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Fioricet	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
G-1 capsules	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
IDE-cet	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per tablet)
Isocet	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per tablet)
Isopap	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Margesic	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Medigesic	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per tablet)

continued

Name of exempted preparation Nom de la préparation exemptée Nombre del preparado exento	Composition of exempted preparation Composition de la préparation exemptée Composición del preparado	
Pacaps	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Pacaps, modified formula	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Phrenilin	Acetaminophen Butalbital	325.0 mg 50.0 mg (per tablet)
Phrenilin forte	Acetaminophen Butalbital	650.0 mg 50.0 mg (per capsule)
Repan	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per tablet)
Repan	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Rogesic	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)
Sangesic	Acetaminophen Butalbital Salicylamide	200.0 mg 30.0 mg 200.0 mg (per tablet)
Sedapap-10	Acetaminophen Butalbital	650.0 mg 50.0 mg (per tablet)
Tencet	Acetaminophen Butalbital Caffeine	325.0 mg 50.0 mg 40.0 mg (per capsule)

continued

Name of exempted preparation Nom de la préparation exemptéé Nombre del preparado exento	Composition of exempted preparation Composition de la préparation exemptée Composición del preparado	
Tencet	Acetaminophen	325.0 mg
	Butalbital	50.0 mg
	Caffeine	40.0 mg
		(per tablet)
Triad	Acetaminophen	325.0 mg
	Butalbital	50.0 mg
	Caffeine	40.0 mg
		(per tablet)
Triad	Acetaminophen	325.0 mg
	Butalbital	50.0 mg
	Caffeine	40.0 mg
		(per capsule)
Triaprin	Acetaminophen	325.0 mg
	Butalbital	50.0 mg
		(per capsule)
Two-dyne revised	Acetaminophen	325.0 mg
	Butalbital	50.0 mg
	Caffeine	40.0 mg
		(per tablet)

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COMMISSION ON NARCOTIC DRUGS
Thirty-fourth session
Vienna, 30 January-8 February 1991
Item 3 of the provisional agenda*

IMPLEMENTATION OF INTERNATIONAL DRUG CONTROL TREATIES

Addendum

Cumulative index of national laws and regulations relating to the control of narcotic drugs and psychotropic substances published in the E/NL. series for the period 1987-1990

Note by the Secretariat

E/NL. series

1. The E/NL. series of published laws and regulations concerning narcotic drugs and psychotropic substances was established in 1947 in response to a request by the Commission on Narcotic Drugs. At its first session in 1946, the Commission observed that several articles of the conventions on drug control** required the parties to the conventions to communicate laws and regulations to one another through the good offices of the Secretary-General. The E/NL. series was designed to facilitate compliance with that obligation. The same series now covers similar requirements for the exchange of legislation established by more recent international treaties on narcotic drugs and psychotropic substances.*** The United Nations

*E/NL.1991/1/Rev.1.

**The International Opium Convention of 1912, article 21; the Agreement concerning the Manufacture of, Internal Trade in and Use of Prepared Opium of 1925, article 30; the Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs of 1931, article 21; and the Convention for the Suppression of the Illicit Traffic in Dangerous Drugs of 1936, article 16 (see Official Records of the Economic and Social Council, Fourth Session, 1946, Supplement No. 1, annex I).

***The Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs of 1961, article 18 (United Nations, Treaty Series, vol. 976, No. 14152); and the Convention on Psychotropic Substances of 1971, article 16 (United Nations Treaty Series, vol. 1019, No. 14956).

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Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (E/CONF.82/15 and Corr. 2), which entered into force on 11 November 1990, also establishes similar requirements, with respect to both legislation concerning confiscation (article 5, subparagraph 4 (e)) and general legislation promulgated to give effect to the Convention (article 20, subparagraph 1 (a)). In practice, texts of laws and regulations relating to the control of narcotic drugs and psychotropic substances have also been communicated on a voluntary basis by States that are not parties to the conventions.

2. Texts of laws and regulations are published on a continuing basis, as information from Governments is received by the Division of Narcotic Drugs. The texts received are edited in standard format, translated if necessary into English or French, reproduced and distributed to States parties, non-parties, interested institutions and members of the public. In the 1987-1990 period, 255 texts of laws and regulations from 70 States or territories have been published in the E/NL. series.

Cumulative index of laws and regulations

3. Cumulative indexes have been designed as companion documents to the laws and regulations issued in the E/NL. series, in order to make the information contained in them accessible in convenient form for parliamentary drafters and for general research and reference purposes. To date, cumulative indexes have been issued for the periods 1947-1965 (E/NL.1965/Index), 1966-1971 (E/NL.1971/Index), 1972-1979 (E/NL.1979/Index) and 1980-1986 (E/NL.1986/Index).

4. The current index covers the laws and regulations communicated to the Division and published in the E/NL. series during the period 1987-1990 (see paragraph 3 above). During that period many States have engaged in intense legislative activity in connection with the preparation and adoption of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988. The list of subjects and drug control activities covered by the index has been revised to take into account matters dealt with in that Convention. The following entries, inter alia, have been added: "financial institutions (regulations on, sanctions, penalties)", "identification, tracing of proceeds", "illicit traffic by sea", "investigation into banks, financial or commercial records", "substances used in the illicit manufacture of drugs (monitoring of)", "mutual legal assistance", "Destruction of confiscated drugs and substances", "request for confiscation from foreign countries", "statute of limitations period".

5. The format of the current index has also been amended, as follows, to provide additional information and to facilitate research:

(a) Part I used to be a list of the E/NL. documents of the period in consecutive numerical order with an indication of the country or territory concerned. In the current index, the full title and date of each law or regulation is also given;

(b) A new part V has been included to facilitate thematic research. While part IV is an alphabetical list of the various subjects and specific control activities covered by the index, part V is a list of the same entries grouped under generic headings.

6. The cumulative index for the period 1987-1990 is before the Commission as document E/CN.7/1991/CRP.11. Should the Commission approve the additions made to the previous format, the index will be issued as in the past as a United Nations sales publication.